PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Patrice MARCHE et al. Group Art Unit: 1648

Application No.: 10/586,742 Examiner: Z. LUCAS

Filed: September 26, 2006 Docket No.: 128497

For: COMPOSITION FOR TREATING PATHOLOGY ASSOCIATED WITH MSRV/HERV-W

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the June 13, 2008 Restriction and Election of Species Requirement, Applicants provisionally elect Group I, claims 12–20 and 22, and elect anti-MSRV/HERV-W antibodies, as a species of antibodies, with traverse. At least claims 12-20 and 22 read on anti-MSRV/HERV-W antibodies. At least claims 12, 16, and 18 are generic.

Applicants also provisionally elect multiple sclerosis (species (a)), as a disorder, with traverse. Claims 16 and 17 read on a method of treating multiple sclerosis. Claim 16 is generic to all pathologies associated with MSRV/HERV-W, including multiple sclerosis and schizophrenia.

The Applicants thank the Examiner for withdrawing the previous Restriction Requirement in favor of the new Restriction Requirement affording the Applicants the opportunity to elect a combination of antibodies as provided for in the claims. Nevertheless, Applicants believe that there remains fundamental errors in the Restriction Requirement and,

thus, respectfully request reconsideration of the Requirement, as provided for under 37 CFR §1.143, for the following reasons.

First, Applicants respectfully submit that the requirement to elect between multiple sclerosis and schizophrenia is clearly improper under unity of invention practice. Only claims 16 and 17 are directed to a method of treating a pathology. Claim 16 does not recite a Markush group; therefore, because no alternatives are recited in claim 16, there is no lack of unity of invention in claim 16.

Furthermore, because claims 12–15 are composition claims, they cannot be said to read on a certain pathology, such as multiple sclerosis or schizophrenia. By requiring the Applicants to choose between specific disorders would mean that at least claims 12–15 would be non-elected claims; thus, such a requirement is effectively a restriction requirement between the composition claims and method of treatment claims using that composition, without even giving the Applicants the opportunity to elect the composition claims over the method of treatment claims. Even if the Applicants were given the opportunity to elect between the composition claims and the method of treatment claims, such a restriction requirement would be clearly improper under unity of invention practice for at least the reason that the method of treatment claims require all of the limitations of composition claim 12.

Second, the Office Action requires restriction between "distinct embodiments" that exists within a single claim. However, the Office Action fails to establish that the alternatives recited in claim 12 do not share a "similar nature." *See* MPEP §1850(III)(B).

Furthermore, MPEP §1850(III)(B) also provides:

> When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. (See Examples in Chapter 10 of the International Search and Preliminary

Examination Guidelines which can be obtained from the Patent Examiner's Toolkit link or from WIPO's web site (www.wipo.int/pct/en/texts/gdlines.htm.))

Thus, even though the Office Action asserts that the anti-TLR4 antibody known as HTA125 was known in the prior art (Wang et al., Infection and Immunity, 69(4):2402–06 (April 2001)), this does not necessarily establish that there is a lack of unity of invention between all of the alternatives recited in claim 12. Indeed, Wang's disclosure of using HTA125 as a receptor blocker, by itself, does not anticipate and would have rendered obvious the invention, as a whole, of claim 12. Claim 12 is directed to more than just an antibody; rather it is directed to a composition comprising "at least one antibody [that] inhibits the pro-inflammatory cascade induced by the activation of MSRV/HERV-W" and "a pharmaceutically acceptable carrier." Therefore, the Office Action fails to establish that the technical features as a whole do not define a contribution over the prior art.

For at least the reasons discussed above, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

Respectfully submitted,

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Date: July 14, 2008

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